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| APPLICATION N | О.                    | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---------------|-----------------------|-------------|----------------------|-------------------------|------------------|
| 10/749,513    | 10/749,513 01/02/2004 |             | John Nash            | 0119/0029               | 8687             |
| 21395         | 7590                  | 06/05/2006  | EXAMINER             |                         | INER             |
| LOUIS V       | VOO                   |             | ALI, SHUMAYA B       |                         |                  |
| LAW OF        | FICE OF I             | LOUIS WOO   |                      |                         |                  |
| 717 NOR'      | TH FAYE               | TTE STREET  | ART UNIT             | PAPER NUMBER            |                  |
| ALEXAN        | DRIA, V               | A 22314     | 3743                 |                         |                  |
|               |                       |             |                      | DATE MAILED: 06/05/2006 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |   | 88   |  |  |  |  |  |
|--|---|--|--|--|--|--|--|
|  | Application No.   | Applicant(s)   |  |  |  |  |  |
|  | 10/749,513  | NASH ET AL.  |  |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit   |  |  |  |  |  |
|  | Shumaya B. Ali  | 3743   |  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |   |  |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION  16(a). In no event, however, may a reply be tim  rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE   | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |  |
| Status   |   |  |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 02 Ja   | nuary 2004.   |  |  |  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) This   | This action is <b>FINAL</b> . 2b) This action is non-final.   |  |  |  |  |  |  |
| •  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |  |  |  |  |  |  |
| Disposition of Claims  |   |  |  |  |  |  |  |
| 4) Claim(s) 1-18 is/are pending in the application.  |   |  |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |  |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |  |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1-6,8,10-16 and 18</u> is/are rejected.  |   |  |  |  |  |  |  |
| 7) Claim(s) <u>7,9,16 and 17</u> is/are objected to.   |   |  |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or  | 8) Claim(s) are subject to restriction and/or election requirement.   |  |  |  |  |  |  |
| Application Papers   |   |  |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examine  | r.  |  |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |   |  |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |  |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |  |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |  |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |   |  |  |  |  |  |  |
| a) All b) Some * c) None of:   |   |  |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |  |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |   |  |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  |   |  |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |  |  |  |  |  |  |
| decline attached detailed office action for a list of the defailed depice not received.  |   |  |  |  |  |  |  |
|  |   |  |  |  |  |  |  |
| Attachment(s)  |   |  |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  | 4) Interview Summary<br>Paper No(s)/Mail D  |  |  |  |  |  |  |
| Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)   | 5) 🔲 Notice of Informal F   | Patent Application (PTO-152)   |  |  |  |  |  |
| Paper No(s)/Mail Date 6) Other: <u>detailed action</u> .   |   |  |  |  |  |  |  |

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# **Supplemental Action**

This action would replace previous non-final office action mailed on 5/4/06. Applicant is requested to respond to the supplemental action in the upcoming remark.

#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Fecteau et al. US Patent No. 6,536,435 B1.

As to claim 18, Fecteau et al. disclose method of making a face mask (figure 1, 22) comprising the steps of: molding a first component (22) in a mould from a relatively high temperature plastics material and subsequently molding a second component (14) from a relatively low temperature plastics material directly on said first component while said first component is in said mould (limitation is considered expected result of using a dual short molding or over molding process, see col.3 lines 25-36).

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# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1-6,8,1016 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bierman US Patent No. 2,444,417 in view of WO 03/016018 A1.

As to claims 1 and 8, Bierman discloses a face mask (fig.1, 10) of a plastics material comprising: a relatively soft canopy member having a peripheral sealing edge providing a seal with the skin around the nose and mouth of a patient (see fig.1); a relatively rigid reinforcement member (28), and a gas port (22) by which gas can enter the mask, however does not disclose said reinforcement member being molded integrally with said canopy member as another shot in the dual-shot molding process; said canopy member being molded as one shot in a dual-shot molding process, however such molding process is well known in the art and also taught by Hicks. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the mask of Bierman in view of Hicks in order to construct the mask using dual shot method for the purposes of making two distinct structures as one structure. As to claim 8, combined teaching of Bierman and Hicks discloses structural limitation required to perform the method steps sited in claim 8.

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As to claim 2, Bierman discloses face mask according to Claim 1, wherein said peripheral sealing edge of said canopy member is tapered to a reduced thickness and an increased flexibility at its edge (as disclosed in fig.1).

As to claim 3, Bierman discloses wherein said gas port is provided on said reinforcement member (see fig.1, 22).

As to claim 4, Bierman discloses wherein said gas port has a gas connector projecting therefrom for correction to a gas supply tube, and wherein said port is located in line with the mouth of the patient and said connector is angled such that it projects down when the mask is applied to the patient's face in an upright position (as shown in fig.1).

As to claim 5, Bierman discloses including a valve (see fig.1, 17) separate from said gas port, wherein said valve is arranged to allow air to flow into the mask when there is an inadequate supply at said gas port (see col.2).

As to claim 6, Bierman discloses, wherein said valve is provided on said reinforcement member (see fig.1).

As to claim 10, Bierman discloses wherein said reinforcement member is a frame with a plurality of radially extending arms (see fig.1).

As to claim 11, Bierman discloses wherein two of said arms extend towards opposite edges of mask and are terminated by lateral bars (35,36,40) extending substantially parallel to an edge of the mask.

As to claim 12, Bierman discloses including a harness (34) arranged to extend around the head of the patient, and wherein said lateral bars support a fastener to which said

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harness is attached.

As to claim 13, Bierman discloses wherein said frame includes three arms supporting respectively a gas port a valve to allow gas to enter the mask and a vent that can be opened to allow gas to flow out of the mask (see fig.1).

As to claim 14, Bierman discloses including a harness managed to extend around the head of the patient and wherein said harness is attached at opposite ends with said reinforcement member (as seen in fig.1).

As to claim 15, Bierman discloses wherein the opposite ends of said harness are of triangular shape having a free end extending rearward and wherein the free end is adjustably attachable with a part of said harness (see fig.1).

As to claim 16, Bierman discloses A face mask assembly including a harness (34) and a mask (10), wherein said mask is of a plastics material and comprises: a relatively soft canopy member (12) having a peripheral sealing edge providing a seal with the skin around the nose and mouth of a patient, and a gas port (22) provided on said reinforcement member by which gas can enter the mask, and wherein said harness is arranged to extend around the head of the patient and is attached with said reinforcement member (see fig.1), however does not disclose said canopy member being molded as one shot in a dual-shot molding process; a relatively rigid reinforcement member, said reinforcement member being molded integrally with said canopy member as another shot in the dual-shot molding process, however such molding process is well known in the art and also taught by Hicks. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the mask of Bierman

in view of Hicks in order to construct the mask using dual shot method for the purposes of making two distinct structures as one structure.

## Claim Objections

Claim 16 objected to because of the following informalities: "said reinforcement member" lacks antecedent basis. Appropriate correction is required.

#### Allowable Subject Matter

Claims 7,9, 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-F 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).